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Rules for Food Inspection

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Report Highlights:

On November 18, 2009 China notified "Specifications on Food Inspection and Testing" to the WTO as G/SPS/N/CHN/124. Comments are due on January 17, 2010. This report contains an UNOFFICIAL translation of this draft measure.

Executive Summary:

On November 18, 2009 China notified "Specifications on Food Inspection and Testing" to the WTO as G/SPS/N/CHN/124. Comments are due on January 17, 2010. The proposed date of adoption and entry into force is February 1, 2010.

China's WTO notification describes the regulation as, "According to the *Food Safety Law of the People's Republic of China*, this regulation specifies the working system and procedures for food inspection and testing agencies."

Thanks go to the Embassy of Australia in the People's Republic of China for assistance with this translation.

This report contains an UNOFFICIAL translation of this draft measure.

General Information:
BEGIN TRANSLATION

Rules for Food Inspection
(Draft for comments)

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| Article I | These rules are formulated to regulate food inspections in accordance with “Food Safety Law of the People’s Republic of China” (hereinafter referred to as “Food Safety Law”) and its implementation rules. |
| Article II | These rules apply to food inspection activities conducted in accordance with “Food Safety Law” and relevant provisions. |
| Article III | Food inspection agencies shall be in line with “Accreditation Conditions for Food Inspection Agencies” and conduct inspections after being accredited within the approved scope of inspection in accordance with these rules and Food Safety Standards. |
| Article IV | Food inspection agencies and staff shall have respect for science, abide by professional ethics, and ensure that the data and conclusions issued are objective, fair and accurate; they must not issue false or inaccurate data or inspection reports. |
| Article V | Food inspection agencies and staff shall be independent from all stakeholders involved in the food inspection and have adequate measures to ensure that the staff shall not be under any influence or pressure from improper external business, finance or other activities; commercial bribery should be prevented to ensure the independence, integrity and impartiality of the inspection. |
| Article VI | Food inspection is subject to the food inspection agencies and staff accountability system. Food inspection agencies and staff are accountable for the food inspection reports and independently assume liabilities. |
| Article VII | Food inspection agencies shall ensure laboratory biosafety in accordance with relevant state regulations. |

- Article VIII Where a food safety incident occurs, the food inspection agency shall carry out the correspondent inspection tasks in accordance with the arrangement of due food safety coordinating authority.
- Article IX A food inspection agency shall have a sound organization, specify job responsibilities and authorities, establish and implements a correspondent quality management system tailored to the inspection activities.
- Article X A food inspection agency shall use relevant documents.
- Article XI A food inspection agency shall be equipped with inspectors and technicians with due food inspection capacities, ensure that qualified staff is hired, and set up records for the qualifications, trainings, skills and experiences of the staff.
- The food inspection agency must not hire staff who are forbidden to be engaged in food inspection by state laws and regulations.
- The food inspection agency shall formulate and implement training plans and evaluate the training effect.
- Article XII A food inspection agency shall have labs, apparatuses and equipment, supporting facilities and environment compatible with its inspection capacity.
- Article XIII A food inspection agency shall ensure the normal use of apparatuses and equipment, standard materials, and standard bacteria (viruses).
- Article XIV A food inspection agency shall keep sound records for apparatuses and equipment, standard materials (reference materials), and standard bacteria (viruses).
- Article XV A food inspection agency shall inspect and keep records of supplies such as the standard materials, reagents and consumable materials that influence the inspection results and conduct regular evaluations of eligible suppliers.
- Article XVI A food inspection agency shall conduct sampling in accordance with correspondent standards or the requirements of the food safety regulatory authority.
- Article VII A food inspection agency shall conduct the sample collection, transfer and disposal in accordance with correspondent regulations and keep relevant records.
- The quantity of samples shall meet the needs of the inspection and re-inspection.
- Article VIII A food inspection agency shall confirm the inspection method and conduct the inspection in accordance with the method stipulated in the Food Safety Standards.
- Article XIX Where there is no standard method for food inspection, a food inspection agency can

develop and adopt a non-standard method for the food inspection and be accountable for its reliability.

Article XX The non-standard method developed and adopted under the entrustment of the food safety regulatory authority shall be submitted to the consignor for confirmation, and the food inspection agency shall submit the following documents:

(I) The technical parameters of the qualitative inspection method, including the scope, principles, selectivity, etc.

The technical parameters of the quantitative inspection method includes the scope, principles, linearity, selectivity, accuracy, reproducibility, detection limit, limit of quantization, stability, uncertainty, etc.

(II) Where there is an investigation and inspection of a sudden food safety incident, it is allowed to only submit confirmed data such as the linear scope, accuracy, reproducibility, selectivity, detection limit, or limit of quantization.

Article XXI The original record shall be signed or stamped by the inspection staff. The food inspection report shall have the accreditation logo of the food inspection agency, its public seal, or the special seal of the food inspection agency authorized by the corporate entity, and the signature of the authorized signatory.

Article XXII A food inspection report and original record shall be properly kept.

Article XXIII A food inspection agency shall exercise internal quality control and supervision on the inspection activity, conduct the internal audit and management review in a planned manner, adopt corrective and preventive measures to improve the management system and boost the inspection capacity continuously, and keep records of the quality activities.

Article XXIV A food inspection agency shall take part in the inter-laboratory comparison or proficiency testing in physical, chemical, microbiological and toxicological food inspection at least once a year.

Article XXV The State encourages the food inspection agency to develop and apply advanced technology in inspections. The application of computer technology in laboratory quality management shall meet the requirements in the annexes.

Article XXVI Where the food inspection agency finds unknown substances or non-food raw materials in food inspection entrusted by the food manufacturer, the food inspection

agency is encouraged to make timely reports to its competent authority or the food safety coordination authority above the county level of the area if there is no clear competent authority, and keep copies of the written report, inspection report and original record.

Article XXVII A food inspection agency shall accept the supervision of its competent authority or the authorized agency. The food inspection agency shall accept the supervision of the accrediting body if there is no due competent authority or the authorized agency. The food inspection agency shall report its work to the supervisory body every year, covering at least the fulfillment of tasks, problems found and trend analysis.

Article XXVIII These rules are subject to the interpretation of the Ministry of Health of the People's Republic of China.

Article XXIX These rules come into force as of the release date.

Annex

Requirements on the computer information system in food inspection

- I. The food inspection computer information system refers to the human-machine system comprising of computers, human resources, relevant supporting equipment and facilities (including the network) which collects, processes, stores, transmits, and searches information in accordance with certain application objectives and rules in food inspection activities.
- II. The food inspection computer information system shall conduct the verification in accordance with the following requirements in these rules.
 - No verification is needed in word processing software, statistical software and special microprocessor and data processing programs matching the food inspection; but it is needed in the adjustment (or redevelopment) of software.
- III. The verification by the food inspection computer information system includes:
 - (I) The verification of data completeness and accuracy.
 1. The computer information system has detailed design documents and strictly meets the type, precision, necessity, range and length of all the data and datasets defined.

2. The system can conduct automatic inspection before the use of the input data, after the storage of the produced data, and after the end of the data transmission, and give a warning when an integrity error is found, terminate the process of error and write the relevant information into the system log.
 3. The system design documents shall include reliable security safeguards for the accuracy of data transmission (if the security safeguards for the accuracy of data transmission are MD5 and SHA authentication algorithm, the clear algorithm and description of the application scope shall be given in the design documents); besides, the system can conduct accuracy verification on the data transmitted in accordance with the design (including encrypted sensitive data and non-encrypted data).
- (II) The verification of the system safety
1. The system safety should meet the requirements of above grade-II in “Classification Criteria for Security Protection of Computer Information System” (GB 17859)
 2. The system design documents include detailed security safeguards (including user permissions, roles, security management strategies, system log rules, database log rules, encryption rules for sensitive data, etc), and the system strictly achieves the functions and requirements of these security safeguards.
Note 1: “Rules” include application rules and management rules.
Note 2: The encryption rules for sensitive data should be integrated with permissions, roles and security strategies to ensure that the unauthorized user cannot access, modify and delete any sensitive data.
 3. The system user manual provides suggestions on the system security setting and clearly informs the user on how to minimize the authorization to avoid the proliferation of permissions.
 4. The system meets the needs of security traceability, i.e., the system shall record correspondent system logs and modifications of all the activities (including the recording and modification) conducted by the user (including the system administrator) and retain the original records before the modification.
 5. The system has an automatic and mandatory data backup system and both the hardware and software environment can ensure the normal operation of the backup.

- (III) The verification of the system validity and applicability
1. The system design documents cover the detailed definitions of the system function, module, efficiency, fault tolerance, framework and interface.
 2. The detailed system manual should be equipped, including the instructions, troubleshooting guide, emergency plan, system maintenance and backup logs.
 3. It shall ensure the compatibility of all the interfaces with the follow-up system upgrading and maintenance.
 4. The multi-user computer information system used in food inspection agencies should pass the pressure test for the overall work efficiency and intensity.